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10/578,449	04/04/2007	Yow-Pin Lim	61959US(51580)	2106

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EXAMINER

KOSAR, ANDREW D

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1654

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Rule 312 Communication	Application No.	Applicant(s)
	10/578,449	LIM ET AL.
	Examiner	Art Unit
	ANDREW D. KOSAR	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The amendment filed on 10 March 2011 under 37 CFR 1.312 has been considered, and has been:

- a) ☐ entered.
- b) ☐ entered as directed to matters of form not affecting the scope of the invention.
- c) ☐ disapproved because the amendment was filed after the payment of the issue fee.

Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

- d) ☒ disapproved. See explanation below.
- e) ☐ entered in part. See explanation below.

See Continuation Sheet

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

Continuation of 1 (e) Entered in part. See explanation: The claim amendment, while correcting a typographical error "obstructive" for "obstructed" additionally extends the claims to embrace treating an inflammatory bowel diseases.

It is noted that inflammatory bowel diseases, likely should be 'disease', as it is the generic term for a plurality of disease states, and is known in the singular, not the plural 'diseases'.

However, extension of the claims to embrace IBD would result in an enablement rejection, as IBD is more than just Chron's disease, thus rendering the claim unpatentable in application of the Wands factors, and while not fully discussed, a sufficient number for a prima facie case are set forth below:

(1) Scope of the diseases covered IBD, or inflammatory bowel disease, is a generic term for an entire family of disorders affecting the colon and small intestine, the most important of which are ulcerative colitis and Crohn's disease. Less common forms include lymphocytic colitis, collagenous colitis, radiation enterocolitis, antibiotic associated IBD (also called pseudomembranous colitis), diversion colitis, ischaemic colitis, Behçet's Syndrome, solitary rectal ulcer syndrome (SRUS) infective colitis, pouchitis, ulcerative jejunoileitis (also called ulcerative jejunitis, NGUJI or UJI), Eosinophilic gastroenteritis (EGE), eosinophilic colitis (ECO), and indeterminate colitis (a term used when diagnosis is uncertain). Some disorders, notably SRUS, EGE and EGO are sometimes included as a form of IBD, and sometimes not.

(2) The nature of the invention and predictability in the art: The invention is directed toward medicine and is therefore physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)

(3) Direction or Guidance: That provided is very limited and does not embrace treatment of any IBD, only mentioning treating Chron's in a hypothetical manner.

(4) Skill of those in the art: IBD arises from a range of causes, known and unknown. Ulcerative colitis, Behçet's Syndrome and Crohn's disease, for example, are idiopathic. Ischaemic Colitis arises from partial death of tissue (infarct) due to blockage in the blood supply, e.g. after major abdominal surgery or poor cardiac output in heart disease. Ulcerative jejunitis is a chronic idiopathic process, an often fatal complication of celiac disease and is seen in enteropathy-type T cell lymphoma. Antibiotic associated IBD can occur from therapy with broad spectrum antibiotics leading to overgrowth of *Clostridium difficile* or other organisms such as *Candida*. Radiation enterocolitis arises from radiotherapy of cancer. Infective Colitis can arise from bacteria (e.g. *Shigella*, *Salmonella*, *Campylobacter*, *E. coli*) or Viruses (e.g. Norwalk-like viruses (NLVs), CMV and HSV). Diversion Colitis develops from the diversion of the faecal stream following colostomy or ileostomy, but there are numerous theories as why this disorder arises, including a disturbance in the normal bacterial flora, prolonged contact between bowel mucosa and (presumed toxic) luminal contents, nutrient loss and absence of short chain fatty acids. There is no general treatment for IBD, as treatment depends on form. For example, infective colitis is normally treated by attacking the underlying infection with e.g. antibacterials, and approach not used in e.g. Ulcerative Colitis. Ischaemic Colitis exists in two very different forms: the "transient" form and the "gangrenous" form, and their treatments are radically different. The latter, unlike the former, has no effective pharmaceutical treatment. Pharmaceutical treatment of diversion colitis involves applying a solution with short-chain-fatty acids to the large intestine through irrigation, a procedure not used in other forms of IBD. Treatment of Behçet's syndrome varies to some degree according to severity and location. For example, colchicine (a drug whose exact mechanism of action is not known) is used for mouth and genital ulcers, but for severe disease of the arteries, immunosuppressive agents such as cyclophosphamide are employed. Some forms, such as radiation enterocolitis and SRUS, have no established effective pharmaceutical treatment.

(5) The quantity of experimentation needed: Particularly in view of the above factors, the level experimentation is expected to be undue.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.